

### **REMARKS**

Claims 32-63 are pending in the application. Claims 40 has been withdrawn by the Examiner as directed to a non-elected species. In the Office Action, the Examiner rejected claims 41-51, 56 and 58 under 35 U.S.C. §112, rejected claims 32-39, 41-56, 58-61 under 35 U.S.C. §102 and rejected claims 57 and 62 under 35 U.S.C. §103. The specification and the drawings are objected to.

Applicants appreciate the interview generously granted by the Examiner on April 28, 2010, at which Bruce Snow, Barbara Daniels, and Peter Johnson were present. The current Office Action was discussed, including the priority claim, and the rejections under §112 and §102. The Examiner clarified that the §112 rejection applies to claim 41-50, 51-53, 56 and 58-59. The concepts of 'flat' and 'straight' in view of the current application were discussed. Possible additional limitations were discussed, including the slanted cylindrical shape one of the articular surfaces, the flange, and the combination thereof.

By this paper, Applicants have addressed all the issues and rejections set forth by the Examiner in the Office Action. The priority claim has been clarified. Claims 41, 43-45, 51-53 and 58-59 have been amended to address the 112 rejection. In order to proceed most efficiently toward allowance of the case, previously withdrawn claim 40 has been canceled, and claims 42, 57, and 62 have also been canceled. However, Applicants reserve the right to amend the present case or a continuing application to include the subject matter of the canceled claims. Four new dependent claims 64-67 are presented herein, and include no new subject matter. Support for the new claims is found in at least Figures 27, 31 and paragraph [0124]. Claims 32, 41, 51 and 58 have been amended and include limitations not found in the cited references.

Claim 32 has been amended to include the further limitation of one of the first and second articulating surfaces comprising a sloping partial cylinder. Claim 41 has been amended to include the further limitations of a first articular surface comprising a sloping partial cylinder, the first articular surface further comprising a first orientation feature, the first orientation feature comprising a first straight section formed on the first articular surface. Claim 51 has been amended to include the further limitations of a nucleus with a second articular surface comprising, a first straight section sloping between and contiguous with first and second curved sections of the second articular surface,

wherein the first straight section rests against the first straight portion in a relative orientation between the first and second end plates that provides a preferred lordotic angle between the first and second vertebral bodies. Claim 61 has been amended to include the limitation of a nucleus with a third articular surface that articulates with the first articular surface, the third articular surface comprising, a first straight section sloping between and contiguous with first and second curved sections of the third articular surface, wherein the first straight section rests against the straight portion in a relative orientation between the first and second end plates that provides a preferred lordotic angle between the first and second vertebral bodies. These amendments find support in at least paragraphs [0121-0123], [0125], and [0129]; and in at least Figures 25, 26, and 31, 32-33, and 38-39. In one non-limiting example, an articular surface comprising a sloping partial cylinder is seen in Figures 25, 26 and 31 in which at least flattened or straight section 150 comprises a partial cylinder, which angles or slopes from a higher point where it joins section 152 to a lower point where it joins section 154.

For at least the following reasons, claims 32-39, 41, 43-56, 58-61 and 63-67 are believed to be in a condition for allowance.

#### PRIORITY

This application is a U.S. National Stage application of PCT/US05/23134, which was filed on June 30, 2005 and is published as Publication No. US 2009/0069894A1. The PCT claims benefit of U.S. Provisional applications No. 60/584,240, filed on June 30, 2004, and No. 60/658,161, filed on Mar. 4, 2005.

The Examiner has correctly noted that Figures 25-31 are not present in either Certified Copy of the Foreign Priority Application, which are the U.S. Provisional applications Nos. 60/584,240 and 60/658,161. However, Figures 25-31 are included in the PCT application, which was properly filed on June 30, 2005, and of which the present application is a National Stage Entry. Therefore, Applicants assert the priority date for the elected embodiment is the filing date of the PCT application, which is June 30, 2005.

CLAIM REJECTIONS – 35 U.S.C. §112

Claims 41-50, 51-53, 56 and 58-59 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Regarding claims 41-50, Applicants assert that the term 'orientation feature' is not indefinite. The words orientation and feature are used according to their plain and ordinary meanings. The Encarta World English Dictionary defines orientation as 'Positioning: the positioning of something, or the position or direction in which something lies.' A feature is a 'distinctive part: a part of something that distinguishes it' (both definitions retrieved on May 27, 2010). Thus, given these common meanings, an orientation feature may be construed as a distinctive part which positions something. As a non-limiting example, paragraph [0122] of the specification provides: '...the flat section 150 in the middle being oriented to provide a correction angle as described above....' The flat section 150 is called out as a distinctive part, or feature, and is specifically oriented, or positioned. Further, paragraph [0123] of the specification provides 'In the neutral position, the cylindrical surface 156 mates with the flattened section 150 of the nucleus, and sits at an angle that provides a deformity correction as shown in FIG. 31'. The two features (cylindrical surface and flattened section) mate and are oriented or positioned (sit at an angle) to provide a deformity correction in the neutral position, or orientation. Claims 41 and 44 have been amended to more particularly point out these orientation features. Further examples of orientation features are found in the specification in at least paragraphs [094-0097], [0099-0102], [0112-0113], [0115-0117], [0118-0120], [0126-0128], [0130] and [0131-0132], and the accompanying figures.

By this paper, claim 42 has been canceled without prejudice or disclaimer, therefore the rejection under §112 to this claim is moot.

Regarding claims 43-45, 51-53, and 58-59 by this paper these claims have been amended to replace the words 'flat' or 'flattened' with the word 'straight', as discussed in the interview, to more distinctly claim the subject matter. This amendment does not represent an acknowledgement of any conflicting definitions between the words in question. A straight section or portion is straight in at least one cross section; for example flat section 150 in Figure 25 is straight along its highest edge viewed from the lateral perspective of the figure.

Regarding claims 51 and 58, these claims have been further amended to remove the limitation of 'in at least one cross section'.

All of the §112, second paragraph objections have been addressed. Applicants respectfully request withdrawal of the rejection.

#### OBJECTION TO THE SPECIFICATION

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter, specifically for the terms orientation feature and stop member.

Regarding the term 'orientation feature', see the discussion set forth above under the discussion of the 112 claim rejections. Further, the claims are written in accordance with MPEP 2173.01: 'They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification'. The terms 'orientation' and 'feature' are not given any special meaning in this application; instead they are used according to their plain and ordinary meanings. Numerous examples of features which provide orientation, according to the plain and ordinary meanings of those words, are provided in at least paragraphs [094-0097], [0099-0102], [0112-0113], [0115-0117], [0118-0120], [0121-0124], [0126-0128], [0130] and [0131-0132], and the accompanying figures.

Regarding the stop member, Applicants point out Figures 6 and 7, and the accompanying text, which set forth stop member 78.

Applicants assert that the claimed subject matter has adequate antecedent basis in the specification and drawings, and request withdrawal of the objection.

#### OBJECTION TO THE DRAWINGS

The drawings are objected to for not showing every feature of the invention specified in the claims, specifically the hole in the flange recited in claims 57 and 62. By this paper, claim 57 and 62 have been canceled, thus rendering the objection moot.

CLAIM REJECTIONS – 35 U.S.C. §102

Claims 32-39, 41-44, 46-50 are rejected under 35 U.S.C. 102 as anticipated by U.S. Patent Application Publication No. 2004/0233240 to Beaurain et al., hereinafter known as ‘Beaurain’.

Independent claim 32 now recites, *inter alia*, the limitations of an articulating structure comprising first and second articulating surfaces positioned between the first and second bone engagement surfaces, one of the first and second articulating surfaces comprising a sloping partial cylinder, wherein the articulating structure nonresiliently urges the first and second bone engagement surfaces toward a relative anterior/posterior orientation that provides a preferred lordotic angle between the first and second vertebral bodies. Beaurain does not disclose an articulating structure with such limitations; more specifically none of the articulating surfaces disclosed by Beaurain comprises a sloping partial cylinder.

Independent claim 41 now recites, *inter alia*, the limitations of a first articular surface comprising a sloping partial cylinder, the first articular surface further comprising a first orientation feature, the first orientation feature comprising a first straight section formed on the first articular surface. Beaurain does not disclose an articular surface with such limitations; more specifically none of the articulating surfaces disclosed by Beaurain comprises a sloping partial cylinder with a straight section formed on the articular surface.

Since all limitations of the claims are not disclosed by the reference, the reference fails to anticipate the claims. Claims 33-39 depend from claim 32 and are therefore also not anticipated; and claims 43-44, 46-50 depend from claim 41 and are therefore also not anticipated. Claim 42 has been canceled. Withdrawal of the rejection is respectfully requested.

Claims 32-39 and 41-62 are rejected under 35 U.S.C. 102 as anticipated by, or, in the alternative, obvious over U.S. Application Publication No. 2005/0216068 to Marik et al., hereinafter known as ‘Marik’.

Independent claim 32 now recites, *inter alia*, the limitations of an articulating structure comprising first and second articulating surfaces positioned between the first and second bone engagement surfaces, one of the first and second articulating surfaces comprising a sloping partial cylinder, wherein the articulating structure nonresiliently urges the first and second bone engagement

surfaces toward a relative anterior/posterior orientation that provides a preferred lordotic angle between the first and second vertebral bodies. Marik does not disclose, or teach, an articulating surface comprising a sloping partial cylinder. Furthermore, if the invention taught by Marik were modified to incorporate an articulating surface comprising a sloping partial cylinder, it would render the invention unsatisfactory for its intended purpose. Through the reference, Marik sets forth that the invention provide a bias towards a neutral position with central alignment along a longitudinal axis passing through the first and second vertebral bodies. See at least the abstract, paragraphs [0002], [0038], [0040], [0042], [0047-48], [0050-0052], [0058], [0063], [0068-70]. An articulating surface comprising a sloping partial cylinder would not allow such a central alignment to be achieved in Marik's invention.

Independent claim 41 now recites, *inter alia*, the limitations of a first articular surface comprising a sloping partial cylinder, the first articular surface further comprising a first orientation feature, the first orientation feature comprising a first straight section formed on the first articular surface. Independent claim 51 now recites, *inter alia*, the limitation of a nucleus with a second articular surface comprising a first straight section sloping between and contiguous with first and second curved sections of the second articular surface. Independent claim 58 now recites, *inter alia*, the limitation of a nucleus with a third articular surface that articulates with a first articular surface, the third articular surface comprising a first straight section sloping between and contiguous with first and second curved sections of the third articular surface. As set forth above under the discussion of claim 32, Marik does not disclose a sloping partial cylinder, or an articular surface comprising a first straight section sloping between and contiguous with first and second curved sections of the surface. Additionally, incorporation of such a cylinder or surface into the invention disclosed by Marik would render the invention unsatisfactory for its intended purpose, as also set forth previously.

Since Marik does not disclose all limitations of the claims, and modification of the prior art invention would render the invention unsatisfactory for its intended purpose, the prior art neither anticipates nor makes obvious the claims. Claims 33-39 depend from claim 32; claims 43-50 depend from claim 41; claims 52-57 depend from claim 51; and claims 59-61 and 63 depend from claim 58 and are all allowable for the same reasons. Newly added claims 64-65 depend from claim 32 and are allowable for the same reasons as claim 32, newly added claim 66 depends from claim 41 and is

allowable for the same reasons as claim 41, and newly added claim 67 depends from claim 52 and is allowable for the same reasons as claim 52. Applicants respectfully request withdrawal of the rejection.

### **CONCLUSION**

By this paper, Applicants have made an earnest attempt to place this case in condition for allowance. Other than as explicitly set forth above, this reply does not include acquiescence to statements, assertions, assumptions, conclusions, or any combination thereof in the Office Action. For the foregoing reasons and for other reasons clearly apparent, Applicants assert that claims 32-39, 41, 43-56, 58-61, and 63-67 are in condition for allowance. If there are any remaining issues preventing mailing of a Notice of Allowance, the Examiner is respectfully requested to contact the undersigned.

Dated this 14<sup>th</sup> day of June 2010.

Respectfully submitted,

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